EXECUTIVE SUMMARY

For more than 20 years during and after World War II, the United States carried out numerous aboveground nuclear-weapons tests. Many of the tests injected substantial amounts of radioactive material into the atmosphere, and some of it reached ground as nuclear fallout. Many people potentially exposed to radiation from the nuclear-weapons testing program later became concerned that radiation exposure had adversely affected their health. In addition, people employed in uranium mining and milling enterprises in support of the US weapons program were at risk for exposure to radiation from inhaled radon and to other airborne hazards in the mines. Experts concluded that those agents increased the incidence of lung cancer and respiratory diseases in miners above that in the general population.

In part to recognize the potential harm of those exposures, Congress issued an apology and passed the Radiation Exposure Compensation Act (RECA), 42 USC 2210 note, on October 5, 1990. RECA provides compensation to people (or their surviving beneficiaries) who have been diagnosed with specified cancers that scientists consider to be radiogenic or other specified chronic diseases that could have resulted from exposure to other agents, such as silica or uranium dust, associated with weapons-program activities. Eligible claimants include civilian *onsite participants* who were involved in aboveground nuclear-weapons tests at various US test sites in the United States and overseas, *downwinders* who lived in areas currently designated by RECA, and *miners* who were exposed to radiation during employment in underground uranium mines and who meet specified residence or exposure criteria. The act provides compensation payments of $100,000 for uranium miners, $75,000 for onsite participants, and $50,000 for downwinders in whom compensable cancer or one of a defined set of other diseases is diagnosed.

On July 10, 2000, Congress passed the Radiation Exposure Compensation Act Amendments of 2000 (PL 106-245), which revised the original act in several important respects. First, two new claimant categories were added—*uranium millers* involved in the crushing, grinding, and leaching of the ore during the uranium extraction process and *ore transporters*, who typically trucked uranium ore from the mine or mill. The 2000 Amendments also specified additional compensable diseases for all claimant categories, reduced the radiation exposure threshold for uranium miners, modified medical documentation requirements, removed some lifestyle restrictions that had limited eligibility for compensation, and expanded the geographic area for the downwinder claimant category.

Further expansion of the program followed with enactment of the Department of Justice Appropriations Authorization Act (PL 107-273), signed into law on November 2, 2002. That legislation included both technical and substantive changes in RECA. In particular, it provided uranium miners with an additional method of establishing exposure to radiation based solely on their duration of employment in a uranium mine.

The RECA amendments of 2000 also amended Subpart I of Part C of Title IV of the Public Health Service Act to add section 417C, on grants for education, prevention, and early detection of radiogenic cancers and other diseases. Section 417C provides the authority for competitive grants to states, local governments, and appropriate health-care organizations to

initiate and support programs for health screening, education, medical referral, and appropriate followup services for persons eligible under RECA. People eligible for this program are categorized by the nature of their exposure to radiation as defined by 42 USC 2210 note and sections 4(a)(1)(A)(i) and 5(a)(1)(A) of PL 106-245 and in 28 CFR Part 79. Those categories comprise uranium miners, uranium millers, ore transporters, downwinders, and onsite civilian nuclear-weapons test participants. The Health Resources and Services Administration (HRSA) oversee the grants, which make up the Radiation Exposure Screening and Education Program (RESEP).

In September 2002, in response to a congressional mandate (PL 107-206), HRSA asked the National Research Council's Board on Radiation Effects Research to convene a committee to assess recent biologic, epidemiologic, and related scientific evidence associating radiation exposure with cancers or other human health effects and to determine how such information might affect estimates of the magnitude of the associated health risks. The present committee was formed in response to that request. Under the congressional mandate, HRSA charged the committee to consider the issues and make recommendations, on the basis of scientific knowledge and principles, regarding

> A. technical assistance to HRSA and its grantees on improving accessibility and quality of medical screening, education, and referral services;
> B. the most recent scientific information related to radiation exposure and associated cancers or other diseases, with recommendations for improving services for exposed persons; and
> C. whether other groups of people or additional geographic areas should be covered under the Radiation Exposure Compensation Act (RECA) program.

HRSA also requested that the committee provide an interim report to the agency and its grantees. The interim report was organized around items A and B, and was to assist RESEP staff to develop an action plan that is consistent with best medical and educational practices and the current state of science. The emphasis in the interim report was preliminary guidance on the ongoing and proposed activities and not on final recommendations.

To address items A, B, and C above, the committee needed to review the history of RECA and the laws, regulations, and objectives that guide it. In addition, important advances in the science and tools available in radiation dosimetry, radiation biology, and radiation epidemiology needed to be considered for their potential effects on determination of whether the exposed populations covered by RECA are likely to be at greater or smaller risk for cancer as the result of radiation exposure than now estimated. Those issues are described and discussed in this report and are reflected in the committee's findings and recommendations.

Much of the committee's effort was directed at the second and third parts of the statement of task—namely, the most recent scientific information related to radiation exposure and associated cancers or other diseases, with recommendations for improving services for exposed persons; and whether other groups of people or additional geographic areas should be covered

under RECA. The committee considered a range of possible expansions of the downwinder geographic areas.

Conclusions

One concern about the RECA program expressed by many downwinders and other involved populations was that their counties or their cancers were not eligible for compensation. The committee discussed such equity issues extensively and concluded that, to be equitable, any compensation program has to be based to a large extent on scientific criteria and has to make the criteria for inclusion and exclusion explicit. Eligibility for compensation needs to be assessed on the basis of criteria that support and are supported by the principle that "like cases are treated alike." The use of scientific criteria is of particular importance because ionizing radiation is not a potent cancer-causing agent, and the risks for radiation-induced disease are generally low at the exposure levels of concerns in RECA populations. For example, the number of cancers observed in the Japanese atomic-bomb survivors that are attributable to radiation is relatively small, even though many in this population received doses much higher than doses received by most of downwinders. Thus, eligibility for compensation needs to be scientifically assessed.

Accordingly, the committee was particularly attentive to the downwinders' complaints about their ineligibility with respect to RECA. It examined the epidemiologic, radiobiologic, and dosimetric information relevant to downwinders' concerns. The scientific evidence indicates that in most cases it is unlikely that exposure to radiation from fallout was a substantial contributing cause to developing cancer. Moreover, scientifically based changes that Congress may make in the eligibility criteria for compensation in response to this report are likely to result in few successful claims. The committee is aware that such conclusions will be disappointing, but they have been reached in accordance with the committee's charge to base its conclusions on the results of best available scientific information.

Recommendations

The committee offers a large number of recommendations that address the main elements of its charge. If implemented, they will improve the compensation program in both a general way and some specific ways. They will also help to reduce screening that does not provide sufficient health benefit to outweigh the risks it poses. And, they will enhance education about programs and services available to affected populations. The recommendations are presented below; extensive discussion of their scientific justification is given in the chapters noted in parentheses.

1. Congress should establish a process using probability of causation/assigned share (PC/AS) to determine the eligibility of any new claim for compensation for a specified RECA-compensable disease in people who may have been exposed to radiation from fallout from US nuclear-weapons testing. Further, Congress should establish criteria for awarding compensation on the basis of computed distributions of PC/AS for any person making such a claim. (See Chapters 5 and 6.)

- Prior to implementation of the revised compensation program, the National Cancer Institute (NCI) or other appropriate agencies should perform a population-based preassessment of all radiogenic diseases using PC/AS to provide guidance to individuals who might apply for compensation by determining the likelihood any individuals in a given population of being compensated. This analysis would be determined by disease identified, places of residence at the time of exposure, ages at the time of exposure and at diagnosis, and other demographic factors using the PC/AS criteria (including consideration of the upper credibility intervals) established by Congress. The calculation would use data for the maximal doses that such individuals may have received from fallout. In settings where variability is important in evaluating risk, there may be several such defined populations, and each would be evaluated on its own merits. The criteria for evaluating such population-based preassessments should be the same as those established by Congress for compensation of claims under RECA (Note: two committee members provided their own interpretations of issues related to the preaassessment criteria; for detail see Chapter 6). The preassessments should be made for the following two purposes:

    a) To provide guidance to potential claimants and the implementing agency as to which diseases may satisfy the compensation criteria established by Congress.
    b) To provide guidance to potential claimants and the implementing agency as to which population groups or geographic areas may satisfy the compensation criteria established by Congress.

- The recommendation applies to residents of the continental US, Alaska, Hawaii, and overseas US territories who have been diagnosed with one of the specified RECA-compensable diseases and who may have been exposed, including exposure in utero, to radiation from US nuclear weapons testing fallout. Both Nevada Test Site (NTS) fallout and the US fraction of global fallout should be considered.

- PC/AS for any individual should be obtained from an estimate of the radiation dose resulting from US nuclear weapons testing and the risk estimate associated with such dose.

- Uncertainties in PC/AS cannot be avoided and may be part of the compensation decision process. Because of substantial gaps in the existing data, the uncertainties in estimated doses[1] incurred by people exposed to radiation from fallout, and consequently the uncertainties in the associated PC/AS estimate, are large. This emphasizes the need to choose compensation criteria carefully. For example, a

[1] The dose estimates depend on the measured deposition of radionuclides taken at the time of the nuclear weapons tests. Given the very small number of monitoring stations, most estimates represent interpolations over very large areas. Among the 3000 plus counties in the continental United States, fallout monitoring in areas other than a limited region in Nevada and its neighboring states occurred at never more than 95 stations through the years of aboveground US nuclear weapons testing. (See Chapters 5 and 6.)

PC/AS value associated with a high percentile of uncertainty could exceed the criteria for compensation even for some very small median doses. The challenge Congress faces will be to decide if it is best to define criteria that avoid rewarding compensation in cases in which there is very low risk, but the uncertainty associated with its PC/AS is very large, because the connection of these cancers with radiation is not well established or the estimated doses are not well known.

To support the use of the PC/AS process for compensation,

- The Centers for Disease Control and Prevention (CDC) and the NCI or other appropriate agencies should complete dose estimates for all significant radionuclides in fallout from US nuclear weapons testing to the population groups identified above. This should include all the major sources of dose related to US nuclear weapons tests considered to have potential health consequences that the CDC-NCI 2001 draft feasibility study described.

- An updated dose calculator, similar to the existing NCI dose calculator for ^{131}I, should be developed for determining dose to the thyroid and other important organs from fallout. Such an updated dose calculator should be directly coupled to a risk calculator similar to IREP Version 5.3 that can compute PC/AS and propagate uncertainties for establishing credibility intervals.

- NCI or other appropriate agencies should maintain and revise the parameters in the models or calculators for estimating PC/AS based on risk estimates recommended by the National Research Council Committee on Biological Effects of Ionizing Radiation, report number 7 (BEIR VII). Over time, the agency should update the PC/AS calculators with the latest risk parameters.

2. The provision which allows individual states not currently covered under Section 5 of the Radiation Exposure Compensation Act to apply for inclusion under RECA if uranium mining occurred in the state during the January 1, 1942 to December 31, 1971 period should be expanded to include not only uranium mining but also uranium milling and ore transportation occurring during that period in support of the US nuclear-weapons program. (See Chapter 6.)

3. On the basis of currently available scientific evidence, no additional diseases should be added to the list of diseases that should be considered for compensation under RECA. (See Chapter 7.)

4. The appropriate agency should review the data on radiation exposure levels obtained inside dwellings constructed from mill and mine tailings. The committee also recommends that its findings regarding potential health consequences of such exposures be evaluated to determine whether the PC/AS values based on these exposures rise to or exceed the levels used in RECA compensation. (See Chapter 7.)

5. The appropriate agency should review historical data on radon concentrations in off-site areas near tailings piles of uranium mills used to produce uranium for the US nuclear-weapons program. The agency should determine whether exposures to those concentrations in off-site areas could result in PC/AS values that meet or exceed the RECA compensation criteria. If so, the agency should take the necessary steps to have these populations included in RECA. (See Chapter 7.)

6. The radiation doses and estimates of risks from the radioactive releases from all NTS nuclear weapons tests, including underground tests that resulted in atmospheric releases, should be included in determining the PC/AS. (See Chapter 7.)

HRSA also asked the committee to assess the agency's screening program and to consider recommendations that could improve access to the program and improve the quality of its educational and referral services for RECA populations. The intent of this report is to ensure that HRSA's action plan is consistent with best medical and educational practices and the current state of science for identifying people who have cancers and other diseases that are compensable under RECA.

On the basis of its review of the RESEP program data and presentations by HRSA officials and RESEP grantees, the committee offers another set of recommendations about medical screening, compensational screening, and education and outreach; they are

7. HRSA should base RESEP medical screening efforts in asymptomatic individuals on robust scientific evidence that such screening improves health outcomes and that its benefits outweigh its risks. (See Chapter 9.)

8. HRSA should not extend its medical screening beyond the generally accepted screening protocols that apply to the US population at large. However, the committee further recommends that uranium miners, millers and ore transporters also be screened for diseases generally recommended for screening in other mining populations and that uranium millers and ore transporters be screened for chronic renal disease. (See Chapter 9.)

9. Once an individual has been shown to be administratively eligible for compensation under RECA (including employment, residence, or a calculated PC/AS at or above some established cutoff criterion), the individual should be offered medical screening recommended in generally accepted protocols that apply to the population at large. The committee notes that HRSA may want to consider screening for depression in its grantees' medical screening protocols (Note: three committee members dissented from this recommendation; for detail see Chapter 9). (See Chapter 9.)

10. HRSA should regularly monitor and follow screening guidelines developed by the US Preventive Services Task Force and published by the Agency for Healthcare Research and Quality. (See Chapter 9.)

11. HRSA should base decisions about screening primarily for compensation on recommendations drawn from credible scientific evidence that the proposed test provides

reliable information about the presence or absence of specified RECA-compensable diseases. (See Chapter 10.)

12. Any screening carried out under RESEP auspices should be preceded by detailed counseling and informed consent that reflects an understanding of and sensitivity to the culture of the potential screenee. The committee also recommends that counselors, when dealing with screening for compensation, ascertain that individuals proposed to be screened fully understand the associated risks, benefits, and likelihood of potential outcomes of screening. (See Chapter 10.)

13. RESEP screening should be undertaken only if individuals satisfy administrative criteria for compensation before screening. (See Chapter 10.)

14. The Department of Health and Human Services should support development of explicit decision models and approaches to shared decision-making and related tools that enhance the ability of patients to participate in decisions that affect their care and prognosis. In particular, the committee recommends that HRSA take responsibility for similar activities in the domain of compensational screening. (See Chapter 10.)

15. If an individual has established eligibility for compensation, RECA should cover the costs of screening, complications of screening, referrals (followup), diagnosis (workup), and treatment for the RECA-compensable diseases for which such eligibility has been established. (See Chapter 10.)

16. HRSA should change its RESEP funding mechanism from grants to contracts. (See Chapter 11.)

17. The Department of Health and Human Services should ensure that the content of public and professional educational programs be consistent across all entities that HRSA supports through its RESEP program. (See Chapter 11.)

18. HRSA should provide information to RECA populations about other radiation exposure compensation programs for which they might be eligible. The committee also recommends that an advisory organization should review all federal compensation programs related to radiation exposure to determine similarities and differences and that HRSA periodically convene representatives of all programs to address inconsistencies among programs and determine the effects of developments over time in radiation biology, risk estimates, legislation, and regulations. (See Chapter 11.)

19. HRSA should ensure that all public informational materials are written so that members of target populations can understand their contents. (See Chapter 11.)

20. HRSA should undertake an enhanced program of education and communication about the risks posed by radiation exposure for people who may have been exposed to radiation from fallout from US nuclear-weapons testing. (See Chapter 11.)

21. HRSA should undertake an appropriately focused educational program explicating the limitations, the benefits, and the risks of medical screening for many RECA diseases. (See Chapter 11.)

22. HRSA should (See Chapter 11):
    A. Use a standardized method to develop outcomes-based goals and objectives for appropriate planning and assessment;
    B. Identify and evaluate the cost and effectiveness of removal of barriers to program implementation; and
    C. Train staff to identify specific barriers to implementation and develop strategies to overcome them.

The committee recognizes that some of its recommendations will be difficult to implement in a short time. Additional information and improved approaches for addressing radiation risk and fallout doses may change compensation programs, medical screening, screening for compensation, and related education and outreach programs. The task of addressing those issues has been difficult, but the committee accepted the challenge because of the critical need for decisions regarding the future of RECA and RESEP.